PCT/AU03/00790

10/519182

10 Rec'd PCT/PTO 21 DEC 2004

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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PS 3137 for a patent by RIANCORP PTY LTD as filed on 25 June 2002.

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PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

"MULTI SPOT OPTICS IN MEDICAL APPLICATIONS"

This invention is described in the following statement:

This invention relates to therapeutic medical application of laser radiation to the human body.

BACKGROUND

It is known to apply laser radiation to the human body for a number of diverse therapeutic and medicative purposes. An example is the use of relatively high power lasers to ablate tissue internal and external of the human body, a further example includes the use of low power lasers to cauterize visible veins and reduce or eliminate port wine markings in the outer dermis. Various other uses include diagnostic and therapeutic medical application of laser generated radiation to predetermined depths in to the skin and selected organs of the body.

Clearly, the frequency, power level (continuously on or modulated on/off duty cycle of the radiation at the same or changing levels) and characteristics of the laser are determined by the nature of the treatment outcome desired by a clinician.

It is typical to apply the laser radiation by using a hand held device under the control of the clinician or an appropriately trained operator. The laser characteristics are programmed or preset and inherent in all laser devices safety procedures are recommended and complied with.

The area of effective laser radiation onto the relevant tissue or organ is specified at the device design stage and known to the operator. Some devices allow for modification but which rarely allow the application area to cover more than a cm^2.

If an area of tissue to be treated is greater than the effective radiation area of the device then the skill of the clinician is used to relocate the device appropriately over the required area in an appropriate manner. The clinician is then responsible for the delivery of the requisite radiation onto the patient so as to achieve an effective exposure.

It is an aim of the invention disclosed herein to provide an alternative to the above-described method of laser radiation application when used for diagnostic and therapeutic medical applications by providing a heretofore unknown to the inventor device.

BRIEF DESCRIPTION OF THE INVENTION

In a broad aspect of the invention a single laser radiation beam output from a laser device is applied to a mammalian body for a diagnostic and/or therapeutic purpose wherein said single laser radiation beam is constructively and destructively interfered with to produce at least two laser radiation beam outputs for application to said mammalian body.

Specific embodiments of the invention will now be described in some further detail with reference to and as illustrated in the accompanying figures. These embodiments are illustrative, and not meant to be restrictive of the scope of the invention. Suggestions and descriptions of other embodiments may be included within the scope of the invention but they may not be illustrated in the accompanying figures or alternatively features of the invention may be shown in the figures but not described in the specification.

BRIEF DESCRIPTION OF FIGURES

Fig 1 depicts a diffractive optical element located at the output of a laser emission device and shows a multi beam output following the diffractive optical element;
Fig 2 depicts a spot pattern generated by the device of Fig 1; and
Fig 3 depicts a pictorial representation of an array of spot patterns created on a tissue using a single beam laser emission device.

DETAILED DESCRIPTION OF AN EMBODIMENT OF THE INVENTION

Although a particular medical application is described herein and a particular laser emitting device configuration is also described, it should be understood that these details are illustrative only and not meant to be limiting in any way upon the application or configuration of the invention.

Fig 1 depicts a pictorial representation of a device according to the invention having a laser emission device 10 that shows a single beam of laser radiation 12.
The laser radiation although not depicted, may have a number of characteristics such as a predetermined spot size, power, frequency/wavelength and modulation. In a practical application the single beam may be designed to have characteristics suitable for the treatment of lymphoedema. When treating lymphoedema there exist predetermined laser radiation protocols that, in one example, requires that the single spot beam is applied to the armpit of the affected arm of the patient at 17 separate locations.

This is a laborious and time-consuming process for both the clinician and the patient.

It is proposed that by locating a specially designed diffractive optical element 14 (seen in pictorial form a distance D1 from the output of the laser device 10) a multitude of individual laser beams be created. Each of these beams in turn forms a laser radiation spot on or about the area of tissue to be treated, in the example given, the armpit of the patient. Fig. 1 pictorially the treatment area is depicted a distance D2 from the diffractive optical element 14.

Thus the output of a laser device 10 having a predetermined emitting aperture and divergence 12 passes through a diffractive optical element 14 to make the apparent aperture of the device appear much larger. The distance D1 of the diffractive optical element from the laser aperture and the predetermined divergence of the laser determines the distribution of the laser light over the patient.

As is readily apparent, a treatment using the multi-beam laser-emitting device in this example consists of a one step process. The time for delivery of the treatment is clearly much shorter and likely more accurate than the prior process.

As will be discussed other optical elements can be included in the apparatus such as focussing optics to make each of the multiple spots have particular size etc. In

experimental apparatus the laser diode used is highly divergent. If that apparatus were required to deliver 17 laser spot treatments over a given area and time, the apparatus would need to be held off the tissue of the patient by some distance to keep the spot size of the laser the same as if it were in contact mode. It is possible to use some lenses prior to or even after the multi-spot optics proposed in this disclosure.

It is also conceivable to use a higher-powered laser to reduce the treatment time. In which case it might be useful to also use a device known as a homogeniser to keep the whole apparatus within class 1 limitations. This is one alternative but there are other applications where class 1 limitations are not required or warranted.

The spread and characteristics of the array of beams emitted by the laser device can be defined and controlled at the time of manufacture of the device. In particular a specially designed diffractive optical element splits the single laser beam into two or more beams. Those beams do not have to be circular when they land on the skin surface patient but could be arranged to be a set of lines or ellipses, or other shapes in an appropriate configuration. The distribution of the power of the beams/lines can also vary. Although this is not quite as easily done, it is possible.

In the illustrated embodiment the multiple beams are arranged especially to create a predetermined beam configuration and characteristic. The manufacturing process of the diffractive optical element determines that the multiple beams are each of the same power distribution or that they may have a distribution that ranges from, a graduated radial distribution to homogenous over its area. It is also possible for the manufactured diffractive optical element to provide multi beam arrays that have an even spread or that cluster in some predetermined way.

Fig 2 is an example of the spot pattern generated by a diffractive optical element wherein each beam has a graduated power distribution and resultant spots that are evenly spread over a predetermined area.

When using a diffractive optical element it may be necessary to use a higher laser power at the source 10 to ensure that each of the multiple beams have the requisite power to effect the desired diagnostic or therapeutic outcome.

Furthermore, the spacing of the diffractive optical element from the patient will need to be gauged so as to ensure the desired radiation level and area of coverage is achieved on the skin or organ to be irradiated. The means of gauging that distance are many and varied. In one embodiment the gauge may comprise a plastic or metal frame that has and abutment surface for sliding or positioning on the area to be irradiated at the other end is fixed relative to the optical element or the structure that positions it from the source laser output. This arrangement is not illustrated in the figures because it is readily mechanically provided and the principle could be put into practice in many ways.

A disposable patient abutment surface is possible so that procedures can allow for a different or new sterile apparatus for each use of the device so as to prevent cross contamination. This may be an issue when some patients will suffer related or sometimes unrelated skin disorders, such as ulcers or non-healing pressure sores. Then there are application differences, where for example the area to be treated varies between large and small or is located in an awkward to get to area of the body.

In another embodiment the laser output is provided to the diffractive optical element via an optical fiber or like functioning laser energy conduit (not shown).

The size and power of the one or more lasers illuminating the diffractive optical element may or may not be the same and as such the one or more of the multiple laser beams being out put from it will vary as required

Fig 3 is used to crudely illustrate the spot pattern that could be created by a clinician using a single beam laser radiating device and it is illustrative to note the inconsistency of the distribution that results in some areas being irradiated twice and other areas missing out completely.

Contrast the irradiation result pictorially represented in Fig 3 with the radiation result depicted in Fig 2 showing a uniform distribution of laser beam spot energy. Combine that with the speed with which the radiation is applied by a single application of radiation by the device being used by the clinician and the benefits are visually apparent.

Indications are that the simultaneous application of laser radiation in the case of lymphodeama treatment has the same effect, if not a marginally better effect than when a single laser beam emission device is used by a trained operator.

Laser ablation of tissue is a further example of a possible use of the arrangement where power and beam focus is appropriate for surgical applications etc.

It will be appreciated by those skilled in the art that the invention is not restricted in its use to the particular application described. Neither is the present invention restricted in its preferred embodiment with regard to the particular elements and/or features described or depicted herein. It will be appreciated that various modifications can be made without departing from the principles of the invention. Therefore, the invention should be understood to include all such modifications within its scope.

Dated this 25th day of June 2002

RIANCORP PTY LTD
By its Patent Attorneys
MADDERNS

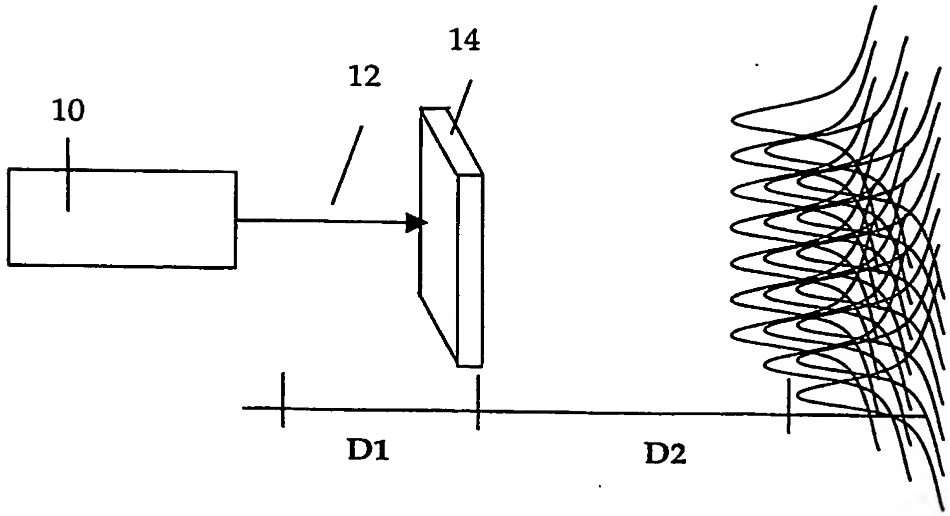

Fig. 1

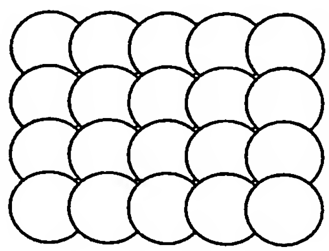

Fig. 2

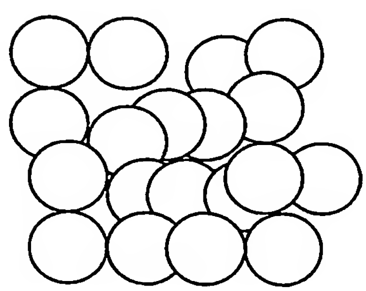

Fig. 3